

**REMARKS**

Claims 1 and 4-10 are pending in this application. Claims 2 and 3 were previously canceled. Claims 11-22 stand withdrawn from consideration as a non-elected group under the restriction requirement. Claim 1 is amended, the support for which can be found in the specification at, among other places, page 3, lines 11-17; page 6, lines 12-19; and page 9, line 28- page 10, line 2. No new matter is introduced by the amendment.

**Final Office Action dated May 28, 2004**

The United States Patent and Trademark Office issued a Final Office Action, mailed May 28, 2004, finally rejecting the pending claims. The Examiner stated in the Action that the claims are not in condition for allowance for the following remaining reasons, to each of which Applicants respond:

**Rejection under 35 U.S.C. §102(b)**

The Action rejects claims 1 and 4 under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 5,716,359 to Ojima et al. Claim 1 has been amended to more particularly recite what Applicants regard as their invention.

In contrast to the recitation of amended claim 1, Ojima describes a protective cover (referred to as “anchor” by Ojima), which is inserted into a hole pre-drilled into bone. Then a bone anchor (referred to as “screw” by Ojima) is implanted into the cover, breaking the cover into pieces. Ojima fails to disclose a bone anchor substantially encapsulated in a protective cover prior to implantation into bone as recited by claim 1. As described at page 3, lines 15-17 and page 6, lines 12-19 of the specification of the instant application, an important advantage of the bone anchor being encapsulated prior to implantation is that it reduces injuries resulting from bone anchor implantation procedures, for example, puncture of a doctor’s glove, abrasion of the patient’s tissue, or insertion of the bone anchor tip into tissue other than the target tissue. Another advantage of the bone anchor being encapsulated prior to implantation, as described at page 3, lines 18-24; page 6, lines 15-19; page 9, lines 1-9; and page 10, lines 1-10 of the specification of the instant application, is that the bone anchor is kept sterile effectively prior to and during surgical insertion of the bone anchor into bone.

Since Ojima fails to teach or suggest a bone anchor encapsulated prior to implantation, as recited in amended claim 1, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. Since claim 4 depends from claim 1, and was rejected for the same reason as claim 1, Applicants respectfully request that the Examiner withdraw this rejection also.

Rejection under 35 U.S.C. §103(a)

The Action rejects claim 5 under 35 U.S.C. §103(a) as being unpatentable over Ojima in view of U.S. Pat. No. 5,637,631 to Kitada et al. As described above, Applicants submit that Ojima fails to teach or suggest all the elements of amended claim 1, the claim from which claim 5 ultimately depends. Kitada fails to overcome the deficiencies of Ojima. Kitada describes a process for preparing a degradable copolymer of aliphatic polyester. In the background section cited by the Examiner, Kitada describes polylactic acid as brittle. Kitada fails to teach or suggest a bone anchor substantially encapsulated in a protective cover prior to implantation into bone, which are the elements Ojima fails to teach or suggest. Therefore, the combination of Kitada with Ojima fails to render claim 1 obvious, and consequently, fails to render claim 5 obvious.

The Action rejects claims 6, 7, 9, and 10 under 35 U.S.C. §103(a) as being unpatentable over Ojima in view of U.S. Pat. No. 5,545,178 to Kensey et al. As described above, Applicants submit that Ojima fails to teach or suggest all the elements of amended claim 1, the claim from which claims 6, 7, 9, and 10 ultimately depend. Kensey describes a system and method for sealing a percutaneous puncture extending into internally located tissue such as the peritoneum. One aspect of Kensey's invention which the Examiner cited is that the anchoring member of the sealing device may include or be coated with an antibiotic. The location cited by the Examiner in Kensey fails to teach or suggest a bone anchor substantially encapsulated in a protective cover prior to implantation into bone, which are the elements Ojima fails to teach or suggest. Therefore, the combination of Kensey with Ojima fails to render claim 1 obvious, and consequently, fails to render claims 6, 7, 9, and 10 obvious.

The Action rejects claim 8 under 35 U.S.C. §103(a) as being unpatentable over Ojima in view of WO 99/37216 to Gellman et al. As described above, Applicants submit that Ojima fails to teach or suggest all the elements of amended claim 1, the claim from which claim 8 ultimately depends. The location cited by the Examiner in Gellman describes a protective sheath that is, for

example, a balloon or gelatin structure, to be mounted over a bone anchor. The sheath may contain an antibiotic which is released when perforated by the bone anchor. The location in Gellman cited by the Examiner fails to teach or suggest a bone anchor substantially encapsulated in a protective cover prior to implantation into bone, the cover comprising a brittle mass. Therefore, combination of Gellman with Ojima fails to render claim 1 obvious, and consequently, fails to render claim 8 obvious.

Since none of the combinations teach or suggest a bone anchor substantially encapsulated in a protective cover prior to implantation, the cover comprising a brittle mass, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of the claims on this ground. In view of the above, Applicants submit each of the presently pending claims in this application is in condition for allowance. Accordingly, Applicants respectfully request the Examiner to pass this application to issue.

Please charge our Deposit Account No. 18-1945, under Order No. MIY-P01-013 which the undersigned is authorized to draw for the applicable fees associated with the Request for Continued Examination filed concurrently herewith. Applicants believe no additional fee is due with this amendment. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P01-013.

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Respectfully submitted,

By 

Erika Takeuchi

Registration No.: 55,661  
ROPES & GRAY LLP  
45 Rockefeller Plaza  
New York, New York 10111-0087  
(212) 497-3625  
(212) 497-3650 (Fax)  
Attorneys/Agents For Applicant